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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,500	06/19/2006	Toyohiko Takushige	SHOBA5.001APC	3693

20995 7590 03/18/2010
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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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03/18/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/583,500	Applicant(s) TAKUSHIGE ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed November 9, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 - Obviousness

Claims 7-8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vermeer (US Patent# 5624906). The rejection is maintained.

Applicant's Arguments

Applicant argues there is nothing in the Vermeer that suggests the combined use of PEG-400, PEG-600, PEG-4000 and propylene glycol, or the beneficial effects obtained when this particular combination is used. Not only does Vermeer not disclose the specific combination of compounds recited in present claim 7, it would not be obvious to choose this specific combination since the combination results in enhanced

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penetration of the composition into a tooth, as evidenced by the enclosed Rule 132 declaration.

The data presented in Tables 1 and 2 of Experiment 1 of the Rule 132 Declaration demonstrate that the penetration of Sample Nos. 2, 5, and 6 that solely employ propylene glycol, PEG-600 or glycerin, respectively, is extremely inferior to that of Samples Nos. 3 and 4, the combination of PEG-400, PEG-4000 and PG, as well as PEG-4000 and PG, both possess excellent penetrability.

Examiner's Response

The reference discloses the use of humectants including polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 4000 and propylene glycol. These are included in a list comprising about 30 suitable humectants, most of which are polyethylene glycol humectants. The reference also discloses these humectants may be used in mixture, thus, suggesting the combination as recited in instant claim 7. The Declaration will be discussed below.

Declaration filed under 1.132

The declaration discloses two experiments, one of which penetrability results and the second shows a Figure displaying a state of tooth penetration of red food coloring.

The first experiment consists of six samples. The first (1) being water, the second (2) propylene glycol, the third (3) Solbase (polyethylene glycol (PEG) 400 and 4000) and propylene glycol in a 1:1 mixture, the fourth (4) polyethylene glycol and propylene

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glycol in a 3:1 ratio, the fifth (5) polyethylene glycol 600 and the sixth (6) glycerin. The results show that 3 and 4 showed the best results out of the six with a migration distance in mm of 5.0 and 9.5 at 24 hours and 16.0 and 18.5 at 48 hours respectively.

The second experiments consist of two samples. Sample 7 comprising polyethylene glycol 400, polyethylene glycol 4000 and propylene glycol, and sample 8 comprising polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 4000 and propylene glycol. Figure 2 is reported to show that sample 8 penetrates the tooth more deeply than sample 7 where PEG 600 is absent.

Applicant argues, as noted in the Declaration, the tooth penetration of a base including PEG-400, PEG-600, PEG-4000 and propylene glycol as recited in present claim 7 is superior to that exhibited with a base including PEG-400, PEG-4000 and PG (which lacks PEG- 600). This can be seen in Figure 2, the base containing PEG-400, PEG-600, PEG-4000 and propylene glycol penetrated to the tip of the tooth, whereas the base containing PEG-400, PEG-4000 and propylene glycol exhibited significantly less penetration. Although Fig. 2 as submitted is not in color, the staining by the red food color is clearly visible as the darker area on the teeth. This result is quite unexpected in view of the poor penetrability of PEG-600 alone.

Examiner's Response to Declaration

The Declaration is insufficient to overcome the rejection. In regard to Experiment 1, it is not disclosed how much of each component is used in the samples other than the mass ratio, and the declaration does not provide the amount of sample that is

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incorporated into the tooth. This is critical because it would appear the concentration would affect penetration of the sample. Further the amount of polyethylene glycol 4000 in combination with propylene glycol is in a 3 to 1 ratio whereas sample 3 discloses solbase and propylene glycol in a 1:1 ratio. This does not appear to be proper comparison since polyethylene glycol 4000 is not in a 1:1 with propylene glycol, as in the case of solbase and propylene glycol. Thus, it is difficult to ascertain whether the better result is based on an excess of polyethylene glycol 4000 in sample 4. The declaration also fails to disclose the results of a sample comprising only polyethylene glycol 400 and polyethylene glycol 4000. Therefore it is difficult to independently conclude if the results reported for samples 3 and 4 are unexpected or additive.

In regard to Experiment 2, the amount of each component in the sample or the ratio of each component with one another is not disclosed by the declaration. The concentration would appear to have an affect on the intensity of the dye and the migration of the dye. It does appear that in sample 2, the dye reached a lower depth of the tooth than that of tooth 1, where it appears that most of the dye is located in the middle of the tooth. However, there is no Figure showing how the tooth originally looked before the incorporation of dye and thus, it appears that tooth 2 was originally darker than tooth 1 when making the assumption that the dye migrated downward and not upward. Therefore based on the Figure and the description of the experiment that is provided, it cannot be independently concluded that the composition used on tooth 2 is better than that used on tooth 1 because the concentration of each sample is unknown and the initial appearance of the teeth are unknown.

Further applicant provides no quantitative data for one to independently determine the migration of the dye as in the case of Experiment 1. It is difficult to assess the migration of a color in a black and white picture.

Even if, for *arguendo*, the results disclosed by the declaration were unexpected, the results are not commensurate in scope with the instant claims. Further, as stated above, it is not disclosed what amount of each component is used and what amounts recited by instant claim 8 are encompassed by the compositions.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612